DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4121. Misbranding of Isopto Alkaline. U. S. v. 26 Cartoned Bottles * * *. (F. D. C. No. 34907. Sample No. 67271-L.)

LIBEL FILED: March 20, 1953, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about December 26, 1952, by Alcon Laboratories, Inc., from Fort Worth, Tex.

PRODUCT: 26 cartoned bottles of Isopto Alkaline at New Orleans, La. Examination showed that the product was contaminated with Pseudomonas aeruginosa.

LABEL, IN PART: (Bottle) "15 cc. Isopto Alkaline Alcon Brand Of Physiologic Methyl Cellulose Ophthalmic 1% with Benzalkonium Chloride 1:50,000 in saline solution INDICATIONS: As a vehicle for Ophthalmic drugs, which are stable in an alkaline (pH 7.4) menstruum. Directions: One to two drops in eye(s) three times daily, or as directed by Physician."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, namely, as a vehicle for ophthalmic drugs, used 3 times daily.

DISPOSITION: May 4, 1953. Default decree of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4122. Misbranding of dextro-amphetamine sulfate tablets and secobarbital sodium capsules. U. S. v. Clyde King (Clyde King Drug Co.), and Benjamin H. Darnell. Pleas of guilty. Fine of \$50 against each defendant. (F. D. C. No. 34841. Sample Nos. 46279-L to 46283-L, incl., 46285-L.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against Clyde King, trading as the Clyde King Drug Co., Birmingham, Ala., and Benjamin H. Darnell, a pharmacist for the company.

NATURE OF CHARGE: On or about July 18, 21, 26, 28, and 29, 1952, while a number of dextro-amphetamine sulfate tablets and secobarbital sodium capsules were being held for sale at the Clyde King Drug Co., after shipment in interstate commerce, various quantities of these drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

Clyde King was charged as a defendant in each of the 6 counts of the information, and Benjamin H. Darnell was joined as a defendant in 3 of the counts.

DISPOSITION: May 25, 1953. The defendants having entered pleas of guilty, the court fined each defendant \$50.

4123. Misbranding of dextro-amphetamine sulfate tablets and methyltestosterone tablets. U. S. v. Holt Chapman (Chapman's Pharmacy). Plea of guilty. Fine of \$50. (F. D. C. No. 34872. Sample Nos. 2456-L, 2640-L, 2644-L, 2649-L, 2656-L.)

INFORMATION FILED: September 15, 1953, Middle District of Georgia, against Holt Chapman, trading as Chapman's Pharmacy, Macon, Ga.

NATURE OF CHARGE: On or about October 22, 27, and 31, and November 12, 1952, while a number of dextro-amphetamine sulfate tablets and methyltestosterone